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APPENDIX

A. CLINICAL RESPONSIBILITIES OF CHIME INVESTIGATORS

CHIME Investigators may serve as the attending physicians and responsible health care professionals for some study infants. The safety, welfare, and optimal clinical care of these infants must remain a high priority. As part of the conduct of the CHIME study, the investigators obtain information about these infants, some of which may be relevant for clinical care. The CHIME investigators have the responsibility to report this clinical information to the appropriate health care provider to ensure optimal clinical care of the patients according to established standards of care and reporting responsibilities. When appropriate, this information may be shared with designated authorities and other relevant care providers, based on the best judgement of the responsible CHIME investigator and in accord with the relevant policies in force at each of the local clinical sites. CHIME investigators are not always the responsible physicians nor do they always have access to complete information on which care can be based. Regardless, when clearly useful information is available it should be given to the responsible physician.

Clinical care issues, when necessary, will take priority over the CHIME research protocol. The specific clinical assessment and intervention decisions will be made by the responsible clinical team at each site, and will not be determined by the CHIME Research Protocol. If the clinical intervention by necessity takes priority over the research protocol, the CHIME Investigator (s) will inform the Data Coordinating and Analysis Center (DCAC) and the NICHD CHIME Research Coordinator through established communications procedures of their actions. The CHIME Investigator will also inform the DCAC and the NICHD CHIME Research Coordinator if it becomes necessary to share clinical information obtained under the CHIME protocol with designated authorities and other relevant care providers.

B. FAMILY MONITOR TRAINING PROTOCOL

1. Family Monitor Training Checklist

Family Monitor Training should be scheduled at intake, within 1 week of enrollment. As part of training, instructors must complete the **Family Monitor Training Checklist (see page V-2)** to insure that all of the essential topics of home monitoring have been covered. The checklist should be filed locally in the subject's chart.

FAMILY MONITOR TRAINING CHECKLIST

Trainer: _____

Date of Training: ____/____/____

Name of Parent(s) or Caregiver(s) Receiving Training:

INFORMATION (check when completed)

1. Demonstrate and Educate Caregiver(s) on the following:

- Function and purpose of the apnea monitor
- Apnea, Bradycardia and Tachycardia
- CPR
- How to put monitor sensors on the baby:
 - patient cable
 - lead wires
 - pulse oximeter
 - electrodes
 - respibands
 - position sensor
- How to operate monitor:
 - on/off
 - reset button
 - battery and charger
 - signal lights and alarms
- When to use the apnea monitor
- How to respond to all patient alarms
- Documentation of alarm events in Alarm Log (Form H5)
- How to clean the monitor, electrodes, respibands and patient cable
- How to respond to mechanical equipment alarms and equipment troubleshooting
- Who to call for the various situations which may occur

2. Review Safety Precautions:

- Importance of grounding equipment
- Explain the importance of **NOT** immersing the monitor or wires in water
- Explain the importance of **NOT** using a switched outlet
- Nursery organization, especially lighting and bedside supplies
- Explain the importance of following protocol
- Give caregiver(s) telephone number for routine and emergency equipment situations

3. Explain Home Visits:

- Explain visiting schedule, down loading procedures and equipment maintenance
- Give the caregiver(s) monitor information and instruction materials
- Collect emergency phone numbers and directions to subjects home
- Procedure for ordering supplies: lead wires, bands and electrodes

4. Administer Parent Knowledge Evaluation Form (H6)

COMMENTS: _____

Family Training Packet

2.

C. PREPARING MONITOR FOR HOME USE

1. Using the *Respi-ECG Simulator*

(From: *NIMS Respi-ECG Simulator Instruction Manual for Operators*)

The Respi-ECG Simulator is a battery powered device which electronically simulates ECG and RespiBand signals. It has been configured for duplicating alarm conditions for testing the RespiTrace PT monitor. For utilization with the RespiTrace PT, the simulator generates a square wave trans-thorasic impedance signal to verify the operation of the impedance channel.

a. Intended Use

The Respi-ECG simulator is designed to provide a convenient, repeatable means of testing the RespiTrace PT alarms and monitoring capabilities. The operator presets the manufacturers suggested alarm parameters in the RespiTrace PT (via the cartridge). The settings are then verified by simulation of the events. The simulator allows the operator to test the following parameters:

- Bradycardia
- Apnea
- Band Off
- Lead Off

b. When to Use

All monitors must be tested with the Respi-ECG Simulator prior to use in the home. Results of the testing should be documented on the **CHIME MONITOR FUNCTION TEST CHECKLIST**.

c. Simulator Features



Visual Indicators

- | | |
|-------------|--|
| 1 Low Batt. | Indicator light flashes when battery is low |
| 2 Heart | Indicator light flashes dim to bright with each simulated heart beat |
| 3 Breath | Indicator light flashes dim to bright with each simulated breath |

Lead Connectors

- | | |
|--------------|-------|
| 4 RC Ribcage | Brown |
| 5 AB Abdomen | Green |
| 6 LL ECG | Red |
| 7 LA ECG | Black |
| 8 RA ECG | White |

Event Activators

- | | |
|-----------|---|
| 9 LO HR | Low Heart rate |
| 10 APNEA | Zero Breathing |
| 11 ON/OFF | Press to turn on, Press again to turn off |



- Sliding panel out in direction of arrow gives access to 9.v battery for removal or replacement.
- Remove battery by disconnecting snaps. Replace battery by re-connecting snaps.

d. Simulator Set Up for Resptrace PT

1. Connecting Patient Cable Leads to Respi-ECG Simulator

Snap the ECG leads to the color coordinating snaps on the simulator (red to red, white to white and black to black)

Snap the Respiband Connectors to the color coordinating snaps on the simulator (green to green and brown to brown)

2. Connecting the Patient Cable to the Resptrace PT

Insert the single-connector end of the Patient Monitoring Cable into the Patient Cable input connector on the front panel of the Resptrace PT. Line up, insert, and screw the cable connector into the input connector to lock it into place.

3. Setting Resptrace PT Alarms Prior to Simulator Test

The simulator is designed to react to the following preset alarm settings. Prior to testing, set the alarm values as indicated below on the Resptrace PT via the Base Station (refer to Base Station manual for details) and the cartridge. For convenience, this cartridge can be labeled as '**Monitor Testing Cartridge**' and kept at the study location where monitor testing is done. Whenever a monitor needs to be tested this cartridge can then be used.

Monitor Testing Cartridge: RESPITRACE PT Alarm Settings				
Monitor Parameter	Alarm	Record	Event Waveform Buffers	
Apnea	20	16	Pre-Record (sec)	75
Hypopnea	-25	-25	Post Record (sec)	30
Labored Breath	-9.0	-9.0	Calibration Values Def. Quan. Val.	400
Rapid Breath	-240	-240	Min. Acc. Vol.	25
Bradycardia	80	80	Periodic Recording Starting Hour	0
Tachycardia	-240	-240	Interval (hours)	1
O ₂ Sat	-50	-50	Duration (minutes)	3
			Continuous Record	OFF - No check mark

WARNING

When using the Respi ECG Simulator place on a surface free and clear of any operating electronic or electro-mechanical device.

WARNING

Keep the Respi-ECG simulator away from the power supply (battery charger) or any motors or other sources of Electro-Magnetic Interference (EMI).

- e. **CHIME Monitor Function Test:** Successful completion of all test items must be accomplished before the RespiTrace PT monitor can be released to a study infant. The testing of the monitor is done in 3 parts: I. Operational testing, II. Simulation of events and III. Verification of simulated events. Each time a monitor is tested, the results must be documented on the CHIME MONITOR FUNCTION TEST CHECKLIST.

I. OPERATIONAL Testing:

Equipment needed: Base Station, RespiTrace PT (with initialized monitor testing cartridge inserted), Patient Cable connected to the Respi-ECG Simulator, oximeter sensor connected to monitor and cable, and the position sensor connected to the monitor and placed on testing surface with the blue dot facing up. Place a check mark under the PASSED column on the Checklist if the item is successfully completed. If an item FAILS - describe the failure in the comments section and then notify the CHIME ENGINEER for documentation of the problem and help with resolution.

1. Verify that the general condition of the RespiTrace PT monitor, cable and battery charger are OK: (i.e. all components are clean, have no visible cracks, no broken connectors, no exposed wires, etc.)
2. Turn on the Respi-ECG simulator. Press ON/OFF button to turn on.
3. Turn on the RespiTrace PT. Make sure the charger is plugged into an outlet and into the PT unit. Slide the ON/OFF switch on the front panel to the ON position. Unit will go through the alarm and power-on light sequence.
4. Front panel lights should flash.
5. Hi/Lo alarm should sound.
6. Charger light should be ON.
7. Wait approximately 20 seconds for the RespiTrace PT to execute its internal diagnostics. Wait 5 mins for RespiTrace PT unit to complete the 5 minute calibration period before proceeding with the Simulation Testing.

II. SIMULATION Testing:

These items will test the proper response of the monitor to various simulated events.

If the item is successfully completed, place a check mark in the PASSED column. If an error occurs, comment on the error and contact the CHIME ENGINEER for documentation of the problem and help with resolution.

8. The HEART light on the PT should be flashing along with the HEART light on the simulator.
9. The BREATH light on the PT should be flashing along with the BREATH light on the simulator.
10. Disconnect one of the brown RC snaps from the simulator. The BAND light will come on and the audible alarm should sound. Reconnect the brown RC snap to the simulator, then press the ALARM RESET button once to clear the alarm.

*(Note: If you press the ALARM RESET **twice** in rapid succession, **you will silence the audible alarm for 60 seconds**. If this happens, wait 60 seconds and try this step again.)*

11. Disconnect one of the green AB snaps from the simulator. The BAND light will come on and the audible alarm should sound. Reconnect the green AB snap to the simulator, then press the ALARM RESET button once to clear the alarm.
12. Disconnect the white RA snap from the simulator. The LEAD light will illuminate and the alarm will sound. Reconnect the white RA snap to the simulator, then press the ALARM RESET button once to clear the alarm. The SLOW light may come on during this test and can be disregarded.
13. Disconnect the black LA snap from the simulator. The LEAD light will illuminate and the alarm will sound. Reconnect the black LA snap to the simulator, then press the ALARM RESET button once to clear the alarm. The SLOW light may come on during this test and can be disregarded.

FYI: Disconnecting the red LL connector will not cause the Resptrace PT monitor to alarm. This is the way the monitor has been designed and does not indicate improper operation.

14. Simulate 10 second BRADYCARDIA. With all the patient cable lead wires connected to the Respi-ECG Simulator and all the alarm conditions cleared, let the simulator run "normally" for 5-10 seconds.

Press and hold the LO HR button for 10 seconds. The red SLOW Heart light will flash on the front Panel of the Resptrace PT. After approximately 5 seconds the audible alarm should sound. Release the LO HR button on the simulator after the full 10 seconds has elapsed. Clear the SLOW HEART light and audible alarm by pressing ALARM RESET once on the front panel of the Resptrace PT.

Wait 35 seconds for the waveform file to be closed. The cartridge has been programmed to record 30 seconds of data after an event has finished. It is

necessary to wait this period of time so that we are assured that each of the simulated events will reside in its own waveform file when the data is downloaded to the Base Station.

15. Simulate 30 second APNEA. Press and hold the APNEA button for 30 seconds. By pressing the APNEA button at the instant the simulator BREATH light is dimmest, the simulator will complete another breath. The time from the last breath to the alarm is 20 seconds \pm 2 seconds. When the alarm sounds write down the time of day on the CHIME Monitor Function Test Checklist (Hour and minute is sufficient). We will use this time to verify that the monitor's clock is set to the right date and time. The APNEA BREATH light will flash on the front panel of the Resptrace PT. Continue to hold the button down for the entire 30 seconds. Then release the button to clear the alarm condition, clear the APNEA light and the audible alarm by pressing the ALARM RESET button once.

Wait 35 seconds for the waveform file to be closed.

16. Oximeter test. Make sure the Pulse Oximeter Cable is connected to the OXIMETER CABLE input connector on the front panel of the Resptrace PT and that an oximeter sensor is connected to the other end of the cable.

Wrap the Pulse Oximeter sensor around your finger. (Follow directions in RESPITRACE PT manual page 18 or detailed instructions enclosed with the Pulse Oximeter sensor probe.) To obtain a clean recording, keep the hand connected to the oximeter sensor as still as possible.

To save the oximeter signal to a waveform file, we need to simulate a BRADYCARDIA so that a waveform file can be created. Press and hold the LO HR button on the Resptrace-ECG simulator for 10 seconds. The audible alarm should sound after approximately 5 seconds. After the 10 seconds has elapsed, release the LO HR button on the simulator, and reset the lights and audible alarm on the Resptrace PT monitor by pressing the ALARM RESET button on the front panel of the Resptrace PT once.

Wait 35 seconds for the waveform file to be closed.

Remove the oximeter sensor probe from your finger.

17. Position sensor test. Make sure the Position Sensor is connected to the POSITION SENSOR input connector on the front panel of the Resptrace PT. Place the position sensor on the table with the blue dot facing UP for ~10 sec. Turn it over, so the blue dot is facing DOWN for ~5 sec. Turn it over, so the blue dot is facing UP for ~10 sec. Turn it over, so the blue dot is facing DOWN for ~5 sec. Turn it over, so the blue dot is facing UP for the remainder of the test.

To save the position sensor test to a waveform file, we need to simulate a BRADYCARDIA so that a waveform file can be created. Press and hold the LO HR button on the Resptrace-ECG simulator for 10 seconds. The audible

alarm should sound after approximately 5 seconds. After the 10 seconds has elapsed, release the LO HR button on the simulator, and reset the lights and audible alarm on the Resptrace PT monitor by pressing the ALARM RESET button on the front panel of the Resptrace PT once.

Wait 35 seconds for the waveform file to be closed.

18. Turn the monitor OFF. Press and hold the ALARM RESET button for 3 seconds then slide the ON/OFF POWER Switch to the OFF position. Remove the cartridge from the Resptrace PT so that the simulations can be downloaded to the Base Station for verification.

III. VERIFICATION of Simulation:

Use the following steps to verify proper Resptrace PT monitor operation during the SIMULATION Testing.

If the simulation testing was done as described above, 5 waveform files should have been created. These waveform files can be printed and compared to the 5 SAMPLE FUNCTION TEST WAVEFORMS enclosed with this document.

The data first needs to be downloaded to the Base Station. Select Data Transfer and then select Download Cartridge to Hard Drive to transfer the recorded data from the cartridge to the TEMP file.

View waveforms by selecting View then selecting Waveforms.

19. Waveform #00: 5 min. Calibration (Test #7).

Select waveform numbered ._00. This waveform was the 5 minute calibration period. The VT, RC, AB, ECG, HR, IMP signals should be similar to those of SAMPLE FUNCTION TEST WAVEFORM #00. A special montage: FUNCTEST.MTG has been distributed to the sites so that the waveforms can be viewed using the same montage as those used to print the comparison waveform files.

Visually verify that all signals are present and similar to those shown in the SAMPLE FUNCTION TEST WAVEFORM #00.

If the waveform file is present and all signals look OK, place a checkmark in the PASSED column on the CHECKLIST sheet for Test #19.

20. Waveform #01: 10 sec. Bradycardia (Test #14). Select Next waveform. This should be waveform numbered ._01. This waveform should contain a BRADYCARDIA approximately 10 seconds in duration. The heart rate should drop to ~45 BPM.

Visually verify that all signals are present and similar to those shown in the SAMPLE FUNCTION TEST WAVEFORM #01.

If the waveform file is present and the BRADYCARDIA was recorded, place a checkmark in the PASSED column on the CHECKLIST sheet for Test #20.

21. Waveform #02: 30 sec. Apnea (Test #15). Select Next waveform. This should be waveform numbered _02. This waveform should contain an APNEA approximately 30 seconds in duration.

Visually verify that all signals are present and similar to those shown in the SAMPLE FUNCTION TEST WAVEFORM #02.

Record the date the computer assigned this waveform on the CHECKLIST SHEET Test #21a.

Record the time of the APNEA assigned by the computer on the CHECKLIST SHEET Test #21b.

IT IS EXTREMELY IMPORTANT TO NOW VERIFY THAT THE RESPITRACE PT MONITOR'S CLOCK IS SET CORRECTLY.

Compare the recorded date of the event (Test #21a) and the date the test was conducted (at the top of the CHECKLIST SHEET). If they are different, then you **MUST** reset the RespiTrace PT monitor's clock using the CLOCKSET procedure and **REDO** the CHIME MONITOR FUNCTION TEST.

Complete Test #21d. by computing the difference in time between what the monitor recorded as the time of the event (Test #21b) with the 'TRUE' time of day when the event occurred (Test #15).

If your site is **NOT** observing Daylight Savings Time then the monitor's recorded time (Test #21b) should be within 5 minutes of the 'TRUE' time of day (Test #15).

If your site is observing Daylight Savings Time then the event's recorded time (Test #21b) should be 1 hour \pm 5 minutes **BEHIND** the 'TRUE' time of day (Test #15).

IF YOU HAVE ANY PROBLEMS WITH THIS PART OF THE TESTING PLEASE CONTACT THE CHIME ENGINEER IMMEDIATELY. RESPITRACE PT MONITOR CLOCKS MUST BE SET CORRECTLY.

If the monitor's clock is set incorrectly, then you **MUST** reset the RespiTrace PT monitor's clock using the CLOCKSET procedure and **REDO** the CHIME MONITOR FUNCTION TEST.

If the waveform file is present and the APNEA was recorded, and the date and time of the event were correct, place a checkmark in the PASSED column on the CHECKLIST sheet for Test #21.

22. Waveform #03: Oximeter Test with 10 sec. Bradycardia (Test #16). Select Next waveform. This should be waveform numbered _03. This waveform should contain a 'good' pulse oximeter signal on the OxiP channel. The SaO₂ should also read in the 90-100% range.

A 'good' pulse oximeter signal is fairly smooth (not jagged) and repeats itself at your heart rate, and is fairly large in amplitude (peak-peak amplitude of >100 computer units).

There should also be a 10 second BRADYCARDIA recorded.

If the waveform file is present, the pulse oximeter signal looks 'good', and the SaO2 levels are 90-100%, place a checkmark in the PASSED column on the CHECKLIST sheet for Test #22.

23. Waveform #04: Position Sensor Test with 10 sec. Bradycardia (Test #17). Select Next waveform. This should be waveform numbered ._04. This waveform should contain 2 transitions on the Pos channel that represent the position sensor being placed in the 'BLUE DOT DOWN' position. (Recall that the position sensor is placed on the BACK of the infant's diaper with the Blue Dot facing UP. Therefore, the 'BLUE DOT DOWN' position in this test is analogous to the infant being in the SUPINE position.)

Verify that the Position signal is similar to the one shown in SAMPLE FUNCTION TEST WAVEFORM #04.

There should also be a 10 second BRADYCARDIA recorded.

If the waveform file is present and the Position signal shows 2 transitions from the PRONE position (Pos=4) to the SUPINE position (Pos=1), place a checkmark in the PASSED column on the CHECKLIST sheet for Test #23.

The Resptrace PT monitor MUST pass all of the tests listed above before it can be released to a study infant. If it fails any of the tests please contact the CHIME ENGINEER for problem documentation and help with resolution.

2. Initializing Monitor Cartridge

After every download and prior to using the monitor, the following procedures must be completed:

STEP #1 Insert a cartridge into the cartridge drive of the computer base station.

STEP #2 Turn **ON** the power switch to the computer base station. Wait for software to load and for "Table of Contents" to appear on display. Then wait 10 seconds.

STEP #3 Select **S** (Setup) either by pressing the "S" key on the Keyboard or moving the cursor with the track ball until Setup is highlighted.

STEP #4 Select **N** (New Patient)

The screen will display a "**Warning: All Data on Cartridge will be erased**".

If **YES**, Select **O** (Okay). If **NO**, download the data on cartridge BEFORE proceeding!! Otherwise the data will be erased!! (For directions on downloading see page ...)

STEP #5 Assign Event Record Label

The **Patient Characteristics** box will appear on the screen. Substitute an Event



Enter remaining fields in Patient Characteristic box

- Enter infant's **Date of Birth** in the format Month/Day/Year
- Enter infant's **Sex** (**M** for Male and **F** for Female)
- Under **ID#** enter the infant's 5 digit **Study ID**
- Enter infant's **Home phone#** (include Area Code, e.g. (617) 638-0000).
- Enter infant's **Home Address** (3 lines available)

In the **Comment** field enter the following information (in capital letters only):

- **Study Group** of infant:
 - AOI** Apnea of infancy
 - HTERM** Healthy Term infant
 - PREM** Premature infant
 - SSIDS** Sibling of SIDS

- Monitor serial # (4 digits)
- Cartridge serial # (last 6 digits)
- The initials of the person who initialized the cartridge



Select **Alt-O** (Okay) to save all information you just entered.



Set Alarm and Record Settings

Determine the infant's "Alarm and Record Settings and Thresholds" for Apnea and Bradycardia. Refer to the charts on **pages V-15 and V-16**, to determine correct monitor Alarm and Record settings appropriate for the infant's **Study Group** and **adjusted age**.

The settings for **Hypopnea, Labored Breath, Rapid Breath, Tachycardia** and **O₂ Sat** **MUST BE TURNED OFF**. Enter negative values to denote that monitor will not alarm for these parameters. Event Waveform Buffers values remain the same for all infants.

HOME USE

NIMS Monitor Alarm and Recording Settings

For Software Version: TOC - 2.0E
EDP - 4.2C

Monitor Parameter		Alarm	Record	Event Waveform Buffers	
Apnea	Healthy Term	40	16	Pre-Record (sec)	75
	All Other Study Infants	20	16		
Hypopnea		-25	-25	Post Record (sec)	30
Labored Breath		-9.0	-9.0	Calibration Values Def. Quan. Val.	400
Rapid Breath		-240	-240	Min. Acc. Vol.	25
Bradycardia	Healthy Term 0-1 month PCA	40	80	Periodic Recording Starting Hour	0
	Healthy Term 1-12 months PCA	40	60		
	All Other Study Infants Preterm-1 month PCA	80	80		
	All Other Study Infants 1-12 months PCA	60	60		
Tachycardia		-240	-240	Interval (hours)	1
O ₂ Sat		-50	-50	Duration (minutes)	3
				Continuous Record	<i>OFF - No check mark</i>

PSG USE

NIMS Monitor Alarm and Recording Settings

For Software Version: TOC - 2.0E

EDP - 4.2C

Monitor Parameter		Alarm	Record	Event Waveform Buffers	
Apnea		90	16	Pre-Record (sec)	75
Hypopnea		-25	-25	Post Record (sec)	30
Labored Breath		-9.0	-9.0	Calibration Values Def. Quan. Val.	400
Rapid Breath		-240	-240	Min. Acc. Vol.	25
Bradycardia	Healthy Term 0-1 month PCA	-40	80	Periodic Recording Starting Hour	0
	Healthy Term 1-12 months PCA	-40	60		
	All Other Study Infants Preterm-1 month PCA	-80	80		
	All Other Study Infants 1-12 months PCA	-60	60		
Tachycardia		-240	-240	Interval (hours)	1
O ₂ Sat		-50	-50	Duration (minutes)	3
				Continuous Record	<i>ON - Check mark present</i>

STEP 9 Select **Alt-O** (Okay) to SAVE all data you just entered. The Screen will display "Table of Contents"

STEP 10 Confirm that **Patient Characteristics are correct**
Select **S** (Setup)
Select **P** (Patient Characteristics)
If all information is correct, select **Alt O** (Okay)

STEP 11 Confirm that **Record and Alarm Settings are correct**
Select **S** (Setup)
Select **R** (Record & Alarm Settings)
If all information is correct, select **Alt O** (Okay)

STEP 12 **EXIT Base Station**
From " Table of Contents"...Select **Q** (Quit)

STEP 13 **Printing Cartridge Settings**
From " Table of Contents"...Select **S** (Setup)

Select **C** (Print Config.pat)

3. Initializing Generic Cartridges

a. When to Use a Generic Cartridge

The procedures listed below should be followed whenever a cartridge is initialized and the infant's **STUDY ID** or **NAME** is unknown at the time of initialization.



Insert Cartridge into Computer Slot

Insert an empty cartridge into the computer drive of the Base Station and **wait 10 seconds**. Pres the <ESC> key. At the Table of Contents:

Select S (Setup)

Select N (New Patient)

The screen will display a "**Warning: All Data on Cartridge will be erased**". If you wish to continue, select **OKAY**.



Completing PATIENT CHARACTERISTICS Information

Since you do not know the name or Study ID of the infant at the time of initialization, an Event Record Label can not be entered in the **NAME** field. Instead type the word **GENERIC** in the **NAME** field. In the **DATE OF BIRTH** field, enter the date of initialization. For **ID #**, we will use a 6 character code. The first 2 spaces reflect the name of the site.

- CH** = Chicago
- CL** = Cleveland
- HO** = Honolulu
- LA** = Los Angeles
- TO** = Toledo

The next four spaces of the **ID #** is the number assigned to this initialization. Sites should number sequentially, starting with 0001.

For example, the first generic cartridge for Los Angeles initialized on November 6, 1993 would have the following PATIENT CHARACTERISTICS:

Patient Characteristics			
Name	Generic		
Date of Birth	11/06/93	Sex	
ID #	LA0001	Tel.	
Address			
Comments			

Leave all other data field in PATIENT CHARACTERISTIC empty.

STEP 8 Set Alarm and Recording Thresholds

Determine infant's alarm and recording settings appropriate for the infant's study group. See **pages V-15 and V-16** for settings.

Select **Alt O** (Okay) to accept settings

STEP 9 Confirm Patient Characteristics and Settings

Select **S** (Setup)

Select **P** (Patient Characteristics)

If all information is correct, select **Alt O** (Okay)

STEP 10 Confirm Record and Alarm Settings

Select **S** (Setup)

Select **R** (Record & Alarm Settings)

If all information is correct, select **Alt O** (Okay)

STEP 11 Document that the cartridge has been initialized

After the initialization is complete, remove the cartridge from the base station and record the **ID #, the date of initialization and the monitor settings** in the **Generic Cartridge Tracking Form**. The **Generic Cartridge Tracking Form** is a running log of all cartridges that are initialized without specific study infant information. Copies of this form should be given to vendors distributing these cartridges for them to fill in: the infant's name, Study ID# and the date the cartridge was placed in the monitor. The master Generic Cartridge Tracking Form should reside with the Study Coordinator at each site.

STEP 12 Place Sticker on Cartridge

Place a Generic Cartridge sticker on the back of the cartridge and write in the **ID #, the date it was initialized and the monitor settings**. The cartridge is now ready to use.

(Reminder: Please contact the DCAC for additional Generic Cartridge stickers.)

STEP 13 Using the Cartridge

The day the cartridge is placed in a study monitor, the infant's **NAME and the DATE IT IS PLACED IN THE MONITOR** should be written on the label on the cartridge and recorded on a copy of the Generic Cartridge Tracking form. (See page V-35 for a copy of the Generic Cartridge Tracking Form)

4. Setting NIMS Monitor Internal Clock

When you run the **CLOCKSET** program on your NIMS Base Station and follow the instructions as they appear on the screen, the date and time of the Base Station will be transferred to the cartridge. The cartridge will be inserted into the monitor. The monitor should then be powered on. The monitor will read the date and time on the cartridge and then reset it's internal clock to that date and time. From then on, records of events and alarms detected by the monitor will be stamped with the correct time and date at which they occurred.

a. When to Change the Clocks

There are two type of clocks that always need to be correctly set. The first is the Base Station clock. This is the clock that will be used to set the clocks in the Respitrace PT monitors. The Base Station clock should always be set to **LOCAL TIME.**

If your site observes Daylight Savings you will need to change the clocks in your Base Station. The switch from Standard to Daylight Savings Time (DST) always occurs at 2:00AM on the first Sunday in April and continues until 2:00AM on the last Sunday in October. When you return to work on the Monday following the DST change in April, you should set your Base Station clock 'ahead' by one hour (i.e. from 9:00AM to 10:00AM). When you return to work on the Monday following the DST change in October, you should set your Base Station clock 'back' one hour (i.e. from 9:00AM to 8:00AM). Refer to section 4b. for instructions on setting the Base Station Clock. Consult the table below for the dates that DST takes effect:

###

###

DAYLIGHT SAVINGS TIME IN EFFECT FROM:

###

Year	First Sunday in April	Last Sunday in October
------	-----------------------	------------------------

###

1993	04/04/93	10/31/93
------	----------	----------

###

1994	04/03/94	10/30/94
------	----------	----------

###

1995	04/02/95	10/29/95
------	----------	----------

###

1996	04/07/96	10/27/96
------	----------	----------

###

1997	04/06/97	10/26/97
------	----------	----------

###

1998	04/05/98	10/25/98
------	----------	----------

###

1999	04/04/99	10/31/99
------	----------	----------

###

###

The Base Station clock must be set correctly before a monitor's clock can be reset. The second type of clock that needs to be set correctly is the clock in the Respitrace PT monitors. Each time you do a Monitor Function Test, you must

document the time that the monitor is set to.

###

If the Resptrace PT's clock is more than 5 minutes off (comparing the event's recorded time with the 'true' local time the event occurred), then it MUST be reset.

Special Note: During the first week in April and the last week in October, the clock in the Resptrace PT will adjust itself for DST changes. This adjustment may happen at any time during that week. If possible, you should postpone Monitor Function Testing until the following week. This will insure that the monitor has adjusted itself for the DST changes. You will then be able to accurately compare the recorded event time with the 'true' LOCAL Time and verify that they are not more than 5 minutes apart. Consult the table below for the dates during which you should NOT perform Monitor Function Tests:

###

IF POSSIBLE, DO NOT PERFORM MONITOR FUNCTION TESTS DURING:

###

###	Year	First Week in April	Last Week in October
###	1993	04/01/93 - 04/07/93	10/25/93 - 10/31/93
###	1994	04/01/94 - 04/07/94	10/25/94 - 10/31/94
###	1995	04/01/95 - 04/07/95	10/25/95 - 10/31/95
###	1996	04/01/96 - 04/07/96	10/25/96 - 10/31/96
###	1997	04/01/97 - 04/07/97	10/25/97 - 10/31/97
###	1998	04/01/98 - 04/07/98	10/25/98 - 10/31/98
###	1999	04/01/99 - 04/07/99	10/25/99 - 10/31/99

###

Special Note for HA: HA does not observe DST. All of the Resptrace PT monitors will adjust themselves for DST. They will jump ahead one hour at some point during the first week in April and then fall back one hour at some point during the last week in October. It will not be practical to reset all of the monitor clocks when these changes occur. Therefore, in an effort to maintain a consistent reference to the 'true' local time, it will be necessary for HA to do the following:

Beginning of DST: Advance the Base Station clocks by one hour (as if they were observing DST.). No changes to the monitors will be necessary because they will advance the time by themselves. Refrain from Monitor Function testing until April 8th.

###

- ### **During DST:** The Base Station clock should always be one hour ahead of the 'true' local time. Monitor Function tests should show that recorded events are 1 hour +/- 5 minutes ahead of the 'true' local time. If they are not, verify that the Base Station is one hour ahead and then run CLOCKSET to reset the monitor clock.
- ### **End of DST:** Set the Base Station clock back by one hour. The Base Station clock and the 'true' local time should now be the same. No changes to the monitors will be necessary because they will reset the time by themselves. Refrain from Monitor Function testing until Nov. 1st.
- ### **After Nov. 1st:** Monitor Function tests should show that recorded events are within 5 minutes of the 'true' local time. If they are not, verify that the Base Station is correct and then run CLOCKSET to reset the monitor clock.

b. Running the CLOCKSET Program

STEP #1 Check that you are at the prompt **C:\NIMS>**

STEP #2 Type **CD CLOCKSET <ENTER>**

STEP #3 Type **CLOCKSET <ENTER>**

An introductory screen will appear giving you further instructions

STEP #4 **Confirm the Date and Time**

Check that the date and time are correct as they appear on the screen. If not, exit to DOS and use the TIME and DATE commands to correct matters. (Refer to a Disk Operating System Manual for further information on these commands).

STEP #5 **Go to the last screen**

The last screen tells you what time and date to expect when you put the cartridge into the monitor. The time on the cartridge is about one minute ahead of the Base Station to give you plenty of time to extract the cartridge, put it into the monitor and boot up.

STEP #6 **Confirm the time setting**

If all goes well there will be the usual 20-second boot-up sequence followed by a 5-second delay after which the front panel lights will start flashing in unison, signifying a successful setting of the clock.

NOTE: If the lights **DO NOT** flash or if you hear a solid alarm tone, setting has failed. Try again from the beginning!!

There is no need to connect sensors or patient cables when setting the clock. Their absence will trigger the warbling alarm tone which you can ignore - it's the solid tone that signifies failure to set the clock.

c. Checking the Clock

This consists simply of running a short recording session, reading the hard drive and checking the recorded data- in this case the time printed in the compliance log or on the waveform plot. The detailed steps are:

STEP #1 **Return the cartridge to the Base Station**

Place the cartridge in the drive and return to the **Table of Contents** by either by pressing the RESET button or by typing "GO" from the NIMS directory.

STEP 8

Select **S** (Setup)

Select **N** (New Patient)

The screen will display a "**Warning: All Data on Cartridge will be erased**". If **YES**, Select **O** (Okay). If **NO**, download the data on cartridge BEFORE proceeding!! Otherwise the data will be erased!! (For directions on downloading see page ...)

STEP 9

Select **Okay** through the patient data and alarm screens

and return to the **Table of Contents**. Verify that the cartridge has zero bytes and then transfer the cartridge to the monitor.

STEP 10

Turn **ON** the monitor's power and let it run for a couple of minutes.

STEP 11

Turn **OFF** the monitor and return the cartridge to the Base Station

STEP 12

Download the cartridge to the Base Station (See page)

STEP 13

Select **V** (View)

View either the Compliance Log or the Waveform to check that the correct time and date are being recorded.

d. Setting the Base Station Clock

The time in the RespiTrace PT monitor can only be as accurate as that in the Base Station. Therefore it pays to continually check the Base Station clock against some standard. A convenient source of accurate time is the U.S. Naval Observatory Master Clock which you can access by dialing 1 (202) 653-1800. A recorded voice will answer and tell you the time every ten seconds.

To set the Base Station use the TIME command in DOS. Type in a time which is, say, 30 seconds ahead of the correct time but hold off pressing ENTER. Then listen to the Master Clock as it calls out successive times. When it reaches the time you have already typed in press ENTER as the beep sounds. In this way you will be able to set the Base Station clock to within a couple of seconds.

Remember: If your site is observing Daylight Savings Time then the time you set the Base Station clock to should be 1 hour BEHIND the 'true' time of day.

5. Storage of Battery Charger

During monitor operation, the battery charger accessory should always be REMOVED from the monitor bag. **DO NOT** attempt to run the charger while it's inside the front pocket of the monitor bag. The charger produces heat which is a potential hazard if left in the bag.

D. MONITOR TRACKING

1. Monitor Use Forms

Monitor Use Forms track actual usage, problems, repairs, returns and transfers of each CHIME monitor. These forms should be faxed to the CTOC a minimum of once per week. Be sure to include all relevant information (i.e. - Study Id and name for newly assigned monitors, location if monitor is a backup or demo unit, etc).

The following summarizes available monitor use "codes" and their definitions:

(1) Just Received - Monitor received from NIMS, CTOC or field use no assessment has been made as to its status.

(2) Needs Testing - Monitor received in tact, awaiting or in process of monitor Testing (Function Test or Biomedical Test).

(3) Available In House - Monitor has passed all testing, ready for use.

(4) Assigned To Infant - Be sure to include Study Id and name of infant.
If this is a backup unit (second unit in home) write **BACKUP** in the comment field.

(5) Problem While In Field - Monitor returned from field with a problem.
Be sure to document nature of problem in comment field.

NOTE: Monitors that remain at code (5) for over two weeks will be flagged on the weekly monitor report. Some sort of problem assessment is expected within two weeks of removal from the field.

(6) Failed Function Test - Monitor failed either the function test or biomedical test. As with code (5), monitors that remain at code (6) for over two weeks will be flagged. Typically, the monitor will move to code (7) and be shipped to NIMS or CTOC.

(7) Returned For Repair - Monitor has been designated for return to either NIMS or the CTOC by the CHIME engineer on call. Specify where monitor is being sent in comment field.

(8) Other Use - Monitors which are not available because they are demo units, PSG units or off site backup units should be entered in the database as a code (8). Use the comment field to specify why this monitor is unavailable for normal use.

(9) Transfer - Monitors that are being transferred from your site to a new location are coded with a (9). These monitors are **NOT** going to be returned to your site.

NOTE: If a log entry is faxed to the CTOC and later found to be in error, **DO NOT** white out or erase the original entry. Simply add a new line with the correct information.

2. Weekly Monitor Use Flags

Once a week the CTOC compares the monitor database with information from NIMS and flags the following conditions:

- (1) Monitors shipped by NIMS/CTOC but not received by site for over two weeks
- (2) Monitors in the database as a code (7) but not received by NIMS/CTOC for over two weeks
- (3) Monitors in database as code (1) - (6) but currently at NIMS for repair
- (4) Monitors in database as code (5) or (6) for over two weeks

Sites will be notified by e-mail from the CTOC for any monitors that get flagged.

3. **Maintaining Adequate Monitor Inventory**

It is important to maintain an adequate backup supply of CHIME monitors at all times to support new enrollment as well as problems that may occur in the field. We have developed a backup ratio that should provide adequate surplus at each site. This backup ratio is calculated as follows:

$$.40(\text{Current enrollment @ site}) + (\# \text{ remote vendor monitors @ site})$$

The # remote vendor monitors for each site was established at the Fall '94 Steering Committee meeting and is as follows:

LA - 4 monitors

HA - 0 monitors

CH - 2 monitors

CL - 2 monitors

TO - 0 monitors

(Toledo's figure was originally 2 but was modified due to the high % of backup monitors in the field there)

If at any time a site feels they need more monitors, please send e-mail to Beccie Mendenhall at the CTOC. Please indicate the quantity needed, delivery time frame required as well as reason (i.e. - increased # monitors in repair, anticipated enrollment, etc). The CTOC maintains enough surplus to handle these extra demands as needed.

4. **Inventory Tracking**

a. **Disposable Inventory**

CHIME "disposable inventory" consists of those supplies used in home monitoring which are discarded after use. These items include ECG electrodes, respibands, oximeter probes and adhesives (Posies). The CTOC will stock disposable inventory every other month on the second Monday of the month. For 1995, the stocking months are Feb, Apr, Jun, Aug, Oct and Dec. The frequency and months chosen for stocking may change based on demand but currently a bi-monthly schedule seems to be working well.

The attached "CHIME DISPOSABLE INVENTORY FORM" is to be filled out by the site prior to each inventory stocking date. Sites should indicate their current in-house inventory for each item. It is important that this count is accurate because the quantity of each item stocked is directly related to the inventory on hand!! In general, sites are stocked as soon as their inventory form is received. If a site feels they are running low

prior to the scheduled stocking date, simply fill out the form and send it with a note requesting immediate stocking. If you run low on a single inventory item and it will be several weeks before the next stocking date, send an e-mail request for that specific item and quantity.

Disposable inventory is stocked based on the current inventory, current enrollment and budgeted usage at each site. The generic usage calculation for each item is as follows:

- Electrodes - 1 set of three per infant per day
- Respibands - 1 set of two bands per infant every 4 days
- Oximeter Probes and Posies - 1 probe/posie pair per infant every 45 days

In addition to the basic budget calculations, each site has a "personalized" adjustment for electrode and respiband size preferences. For example, LA uses 95% Pediatric Jensen electrodes and 5% Huggables while Chicago uses 50% Pediatric Jensens, 20% Large Jensens and 30% Huggables.

After each inventory stocking is complete, the CTOC does an analysis of usage at each site over the last two month period. This analysis can help pinpoint items that are not holding up in the field as long as expected. It also helps tailor the stocking calculations to each individual site's preferences.

b. Accessory Inventory

CHIME "accessory inventory" consists of monitoring equipment outside of the actual infant monitor used in the home. This equipment consists of patient cables, lead wires, position sensors, monitor bags and transport carts and battery chargers. Data storage media is also considered accessory inventory - removable hard drives, DAT tapes and optical disks for data storage and transfer. Since accessory inventory items do not have a budgeted life span, these items will be stocked as needed.

In January and February 1995 sites completed an inventory for their accessory items. Based on this inventory, each site was stocked with enough accessory inventory to support their monitors in stock. There was also a small surplus stocked for each accessory item as follows:

- 3 extra - Patient Cables
 - AB/RC/ECG leads
 - Position Sensors
- 1 extra - Monitor Bag
 - Monitor Cart
 - Battery Charger

Beginning in March, 1995 accessory inventory items will be replaced (stocked) only on demand. Equipment which was returned from the field non-operational will be returned to the CTOC using the "Broken Equipment Transmittal Form". For each piece of broken equipment received, the site will be sent a replacement. Any accessory items lost while in the field should be reported to the CTOC via e-mail or telephone. These items will also be replaced from CTOC stock. Using this method, no further site inventories of accessory items should be required.

E. MANAGEMENT OF EVENTS

Data from Healthy Term infants will not be analyzed by investigators until an infant has discontinued home monitoring, unless a Healthy Term infant has a clinically evident ALTE. Infants in all other study groups will be managed according to event type.

1. Apnea Events

a. Apnea Events between 15-20 seconds

- If an infant has more than 4 apnea events per week with a duration between 15-20 seconds as documented on event recording, then oximetry may be evaluated.
- If there is associated bradycardia or if there are episodes of desaturation ($< 85-90\% > 4$ per week or any episode $< 85\%$), then the infant may be evaluated with the following tests:
 - history and physical examination
 - polysomnogram
 - echocardiogram
 - chest radiograph
 - complete blood count and reticulocyte count
 - if seizures are suspected, one may consider:
 - neurodevelopmental examination
 - magnetic resonance imaging of the brain
 - electroencephalogram
- If all of the above are negative, change alarm limits.

b. Apnea Events 20 or more seconds in duration

- If an infant has any episode of apnea ≥ 20 seconds (with or without bradycardia), as documented by event recording, then oximetry may be evaluated.
- If there are any episodes of desaturation ($< 90\%$) associated with apneas ≥ 20 seconds, then the infant may be evaluated with the following tests:
 - history and physical examination
 - polysomnogram
 - echocardiogram
 - chest radiograph
 - complete blood count and reticulocyte count
 - if seizures are suspected, one may consider:
 - neurodevelopmental examination
 - magnetic resonance imaging of the brain
 - electroencephalogram
- If all of the above are negative, change alarm limits.
- If there are no episodes of desaturation associated with the apneas > 20 seconds then the apnea alarm can be increased to 25 seconds.

2. Bradycardia Events

a. Bradycardia event of 70 bpm

- Bradycardia alarm may be lowered by 10 bpm, until a setting of 70 bpm is reached, **IF**:
- multiple bradycardia alarms documented by parent or by event recording
 - infant **NOT** cyanotic, pale, limp, or requiring intervention
 - infant less than one month of age

b. Bradycardia event of 50 bpm

- Bradycardia alarm may be lowered by 10 bpm, until a setting of 50 bpm is reached, **IF**:
- multiple bradycardia alarms documented by parent or by event recording
 - infant **NOT** cyanotic, pale, limp, or requiring intervention
 - infant's age greater than one month

c. Continued events

- If frequent alarms occur after resetting threshold (> 5 per day on a daily basis):
- infant may be examined, and then have oxygenation assessed with a hemoglobin saturation monitor
 - ECG or Holter may be performed
 - if symptoms suggest GER, following tests may be performed:
 - barium swallow
 - gastroesophageal scintiscan
 - esophageal pH monitoring

3. Parental Report of Events

- If a parent reports an event that required vigorous stimulation or cardiopulmonary resuscitation, the event recording will be reviewed.
- If there is no hard copy documentation of the event, then the family is given reassurance.
 - If there is hard copy confirmation of the event, then the infant will be reevaluated as an ALTE.
 - If the infant was not on the monitor at the time of the event, then the infant will be reevaluated as an ALTE.
 - If an infant is hospitalized for the evaluation of an ALTE, the infant should remain on the event recorder in the hospital.

F. ONGOING MONITOR SUPPORT

1. Weekly Phone Contacts

Each family with an infant in the CHIME study is scheduled to receive a follow-up phone call within the first 24 hours of home monitoring (**H2-PHONE** form) and then weekly phone calls while the infant is home monitored. An **H2-WEEKLY** form must be used to conduct a scripted interview each week either by phone or in person. If an infant is scheduled for a Medical follow-up visit during the week, the **H2-Weekly** may be completed at the visit instead of over the phone (see **Section VI. Medical Follow-up Visits** for more details).

If study personnel are unable to contact the infant's caregivers after 3 attempts (on 3 separate days) in one week, complete the cover page of an **H2-WEEKLY** form. Fill in the dates (Sunday through Saturday of the previous week) that the questionnaire was to address, check the type of weekly contact (**PHONE**) and that it was '**Attempted but Unsuccessful**'. Also write in the infant's name, Study Id, date of birth, your name and the last date during the week you attempted to contact the caregiver under the **Date Completed**.

The next time you are able to reach the caregivers whether it be 1 week or 1 month, an **H2-WEEKLY** should be completed for the previous week's information and an **H2-MISSED** should be completed for the week(s) that an **H2-WEEKLY** was not successfully completed.

a. Loss of Contact with Caregivers

1) An inability to contact caregivers for **2 consecutive weeks** will result in an additional visit and download. (See section **5. Extra Visits** for more details).

2) An inability to contact caregivers for **8 consecutive weeks** either by phone or visits will result in formally ending the home monitoring portion of the protocol for the infant. A **Completion of Monitoring form (I)** should be completed for the infant and sent to the DCAC. Fill in the infant's name, study id, date the monitor was placed in the home, the date of last contact with infant's family and the reason for early discontinuation of monitoring being '**Unable to contact parent(s)/caregiver(s) for 2 months**'. Once an I form is completed for the infant, H2-Weekly forms are no longer necessary. However, every attempt should be made to locate the infant's family and retrieve the CHIME monitor. When the family is located and the monitor retrieved, the Coordinator should complete an H2-Missed form covering the time period of lost contact and notify the DCAC of the 'Date the monitor retrieved from the home' (for the I form).

2. Technical Support - 24 hours

The monitor equipment representative and/or study personnel will be available 24 hours a day by phone to answer technical questions and offer support to parent(s)/caregiver(s). After **ANY** phone contact (other than the **H2-WEEKLY OR H2-MISSED**) with parents or caregivers regarding home monitoring, study personnel must complete a **Phone Contact Report** (Form **H2-PHONE**).

3. The CHIME Engineers

Early in the pilot phase of the CHIME study it was discovered that the new and somewhat complicated monitoring equipment encountered many problems. Sites originally addressed these problems directly with the manufacturer, Non-Invasive Monitoring Systems, Inc. (NIMS), but this approach was found to have some limitations. As a result the Clinical Trial Operations Center (CTOC) established a group of three engineers who were trained in the technical aspects of the use of the monitor and its associated base station. These engineers now serve as the technical trouble-shooting group for the CHIME study.

The CHIME engineers are the point of contact for clinical sites to deal with technical problems. Each week one of the three engineers is on call and is responsible for addressing all problems that occur that week. Many of these problems can be solved by the engineer him or herself while others must be referred to the manufacturer. Personnel from sites should not contact the manufacturer directly. Problems that need to be referred

to the manufacturer will be relayed by the engineer on call.

A database is maintained for all problems referred to the CHIME engineer. A record of the problem and how it was addressed is established for each problem using a system similar to the problem orientated medical record. In this case the mnemonic STAR is used to refer to the four sections of this record:

S - Subjective description of problem.

T - Tests that have been used to further diagnose the cause of the problem.

A - The assessment of the problem by the CHIME engineer.

R - The resolution of the problem.

An example of the **STAR** form is attached to this document.

All problems once entered in the data base must be resolved. Some problems may require that a monitor or other equipment be returned to the manufacturer. It is the responsibility of the engineer on call to arrange for this return with both the manufacturer and the clinical site reporting the problem. Even though the monitor has been returned to the manufacturer, the CHIME engineer on call is still responsible for following the problem and updating the database until that problem has been resolved.

Once a week the CHIME engineers meet with Dr. Neuman of the CTOC along with staff members at NIMS via telephone conference to review each of the problems that have occurred during the week. Progress in addressing unresolved problems from previous weeks is also reported at this meeting. A printout from the database (see attached example) is provided to each participant in this conference, and monitor problems are reviewed in a manner similar to reviewing patients in a clinical conference. As with clinical conferences, this conference takes advantage of the combined wisdom of the participants in addressing monitor problems, provides educational opportunities to improve the problem solving skills of the participants, is a source of valuable feedback to the manufacturer, and provides the opportunity to look for trends in problems so that the manufacturer can develop strategies to avoid similar problems in the future.

In dealing with monitor technical problems, the clinical site should follow the steps listed below.

Step 1 - If a problem is reported for a monitor at home, replace that monitor with a functioning monitor after getting as much of a history related to the problem from the infant's care giver. It is important to document such items as the light pattern on the front panel of the monitor when a continuous alarm occurs, whether all sensors are connected to the infant, and the state of the infant during the alarm. The potentially faulty monitor should be returned to a central location at the clinical site where CHIME personnel can evaluate it more carefully.

Step 2 - The monitor should be evaluated at the clinical site by CHIME personnel using the monitor checklist (See attached). The monitor should be connected to the NIMS simulator during this evaluation. In some cases it may not be possible to complete all of the tests listed on the form due to the problem, and this should be documented. In other cases the monitor may appear to work perfectly well and pass all of the tests indicated on the checklist. If this happens, clinical personnel are asked to turn off the monitor, wait at least

two minutes, and turn on the monitor again allowing it to go through its standard power up processes while attached to the NIMS simulator. After the test of the alarm producing the "high-low warble tone" is completed the "Breath" and "Heartbeat" lights on the monitor front panel should be checked to see if they are flashing at a regular rate corresponding to the heart rate and the respiration rate respectively from the simulator. If these lights are flashing in an appropriate manner, the monitor can be switched off and the test repeated. This should be done at least six times to demonstrate that the monitor is functioning normally. If the monitor fails to function appropriately, the individual performing the test should document over how many of the total number of trials the monitor failed to function.

Step 3 - If the problem continues at the clinical site, the person doing the testing should contact the CHIME engineer on call and describe the problem to him or her providing as much test data as possible.

Step 4 - The CHIME engineer will ask some questions to help her or him diagnose the problem and will often also suggest some simple tests that can be performed by personnel at the clinical site. The results of these tests will further help to identify the problem. Based upon the results of these tests, the CHIME engineer will determine what steps need to be taken. She or he may request that the monitor be returned to the manufacturer, the monitor or a cartridge be sent to the CTOC for evaluation, or that a download from the monitor cartridge be carried out by the site and a DAT tape be sent to the CTOC for evaluation.

Step 5 - The CHIME engineer will follow the problem until an adequate resolution is obtained. CHIME engineers are always happy to receive feedback from the clinical sites regarding the solution of problems or where appropriate indicating that the problem has not been adequately resolved.

IMPORTANT CONSIDERATION: IN CASES WHERE IT IS NECESSARY FOR THE CLINICAL SITE TO RETURN A PIECE OF EQUIPMENT EITHER TO THE MANUFACTURER OR TO THE CTOC, IT IS IMPORTANT THAT THE EQUIPMENT IS APPROPRIATELY PACKAGED FOR SHIPMENT. MONITORS SHOULD ONLY BE SHIPPED IN THEIR ORIGINAL SHIPPING CARTON, AND THE ORIGINAL PIECES OF FOAM PADDING SHOULD BE USED TO SUPPORT THE MONITOR IN ITS CARTON. WHEN IT IS NECESSARY TO SHIP A CARTRIDGE, IT MUST ALSO BE ADEQUATELY PACKAGED AND WRAPPED IN A SHOCK ABSORBING MATERIAL SUCH AS "BUBBLE WRAP". CARTRIDGES ARE EXTREMELY FRAGILE, AND IMPROPER HANDLING OR SHIPPING CAN RESULT IN LOST DATA. THE FABRIC POUCH SUPPLIED WITH EACH CARTRIDGE IS NOT SUFFICIENT PADDING FOR SHIPMENT

4. Routine Monitor Support/Download Visits

Each family with an infant in the CHIME project will receive periodic contacts by the vendor or CHIME staff, to check alarm logs and download data from event monitor. At this time remedial instruction in monitoring procedures and CPR will be carried out.

a. Schedule of Downloads

- 1st download within one week of home monitoring

- 2nd download to occur at one month after intake
- Every 4 weeks thereafter.

Please note that these are the **MINIMUM** number of downloads expected. There should be no more than 4 weeks between downloads. At one month adjusted age, an infant's monitor settings must be changed, with an accepted tolerance limit of +/- one week (i.e. monitor settings changed from 43-45 weeks PCA). If problems are identified by phone or caregivers are noncompliant, a visit should be scheduled for an additional download within 2 weeks of the prior download.

b. Home Visit Procedures

- 1) Arrange for a time for a home visit with the family.
- 2) Observe the general condition of the equipment upon entering the home, i.e. the condition of the monitor, battery charger, patient cable, lead wires and sensors. Also check the condition of the ECG electrodes and respiration bands. Be sure there are extras of each.
- 3) Check the monitor for proper function.
 - Are the indicator lights functioning (breath, heart and pulse)?
 - Is the battery charger plugged in with the CHARGING light on?
 - Is the position sensor on the back of the diaper with the BLUE dot facing out?
 - Is the oximeter sensor being used correctly?
- 4) Review monitoring procedures with parents.
- 5) Replace current cartridge with a newly initialized one. Return the old cartridge to the site for downloading.
- 6) Collect Parent Monitoring Log (H5) & review compliance with parents/caretakers.
- 7) Ascertain if any technical or family issues are of concern to the paren/caregivers. Document the problems and the solutions provided on a **Home Provider Report** (Form **H2-VISIT**).

c. Unsuccessful Home Visits

If several attempts to complete a home visit are unsuccessful:

- 1) Attempt to contact the caregivers by phone. If you are able to reach them, reschedule a home visit. If you are unable to reach them, attempt an unscheduled "drop-in" visit.
- 2) If you are unable to contact caregivers either by phone or in person for 2 consecutive weeks, send the caregivers a registered letter, to inform them that you need to speak

with them.

3) If home visits and phone contacts are unsuccessful for 4 consecutive weeks, complete an Incident Report and fax it to the DCAC. (See page **V-35**)

4) If home visits and phone contact are unsuccessful for 8 consecutive weeks, the home monitoring portion of the study will officially end for the study infant. Complete a Form I (Completion of Monitoring form). Fill in the infant's Study Id, date form completed, the date the monitor was placed in the home and the date caregivers instructed to stop using the monitor by CHIME Personnel. For those caregivers who have been unable to contact for 8 consecutive weeks or more, this is the date of their last contact with CHIME Personnel. For the Reason Monitoring has ended, check **'Unable to contact parent(s)/caregiver(s) for 2 months'**. Send the form to the DCAC in your weekly data packet. Continue to contact caregivers to retrieve study monitor. Once monitor is collected, complete a CHIME Correction/Addition Log, with the infant's Id, the type of (Form I) and the date monitor retrieved from the home.

5. Extra Visits

(A download should always occur at these additional visits.)

a. As Follow-up to phone calls

Additional visits will be made as needed by the vendor or CHIME staff as follow-up to phone calls regarding: full memory, monitor malfunction or other monitoring problems.

b. As Follow-up to reported and/or documented periods of non-compliance

Additional download visits should be scheduled within two weeks of the prior download (as follow-up to periods of non-compliance) if any of the following criteria are met:

- 1) Site personnel are unable to contact family and obtain a parent/caregiver report of monitor use (complete **H2-WEEKLY** form) for 2 consecutive weeks.
- 2) Parent/caregiver reports, either during the weekly phone contact or Medical Follow-up visit, that they **are not always** using the CHIME monitor when the infant is **asleep** for more than half the time during the last week and nonuse is **not attributable** to monitor technical problems.
- 3) Infant's download did not meet the **8-80 rule**, that is: after the site downloads the infant's cartridge and evaluates monitor use (using the H2-DOWNLOAD form) the infant WAS NOT monitored at least 8 hours of monitor use per day, 80% of the time and this noncompliance has not already been addressed during the weekly phone contact (See #2 above).

6. Non-compliance

Home monitoring will be discontinued and a **Completion of Monitoring form (I)** completed for study infants if:

- a. There is monitor nonuse documented for one month or more over 2 consecutive downloads.

OR

- b. CHIME personnel are unable to contact parent(s) or caregiver(s) for 8 consecutive weeks.

7. Incident Reports

a. When to complete an Incident Report (J1) form

An Incident Report form must be completed for any potentially harmful incident that occurs to an infant, caregiver or study personnel involving any aspect of the CHIME study protocol. **An Incident Report Form must be completed and FAXED to the DCAC within 48 hours of the incident.**

b. How to complete an Incident Report (J1) form

- 1) Write in the name(s) of all individuals involved in the incident, (Q#1) the date and time of the incident, (Q#2) whether the incident involved equipment, use of a non-study monitor, potential or personal injury of an infant, caregiver, study personnel, vendor or other individual, (Q#3) the location where the incident occurred and (Q#4) the type of the equipment (if any) involved.
- 2) Describe the incident in clear, concise terms (what happened, who was involved, where did it occur, when did it happen and how) (Q#5).
- 3) Describe the investigation of the incident at the site both planned and completed (Q#6). Include details of the investigation such as the type of data obtained, any testing that was done, interviews or home visits made and results.
- 4) Describe all corrective action taken at the site both planned and completed (Q#7). Include instructions given to caregivers, any treatment of injury or equipment replacement.
- 5) A CHIME Investigator MUST sign and date page 2 of the Incident Report form BEFORE faxing it to the DCAC.
- 6) An Incident Report Form must be completed and FAXED to the DCAC (617-638-5066) **within 48 hours of the site being notified of the incident.**

c. Processing of Incident Reports at the DCAC

For each Incident Report form received by the DCAC, a four digit incident tracking number is assigned. The names of all individuals involved in the incident are removed from the report before copies are faxed to the Project Officer at NICHD (Dr. Marian Willinger) and the CTOC (Dr. Michael Neuman). Some incidents, such as an infant death, may require further review by the CHIME Incident Review Committee (Drs. Lister, Corwin, Hunt, Keens). Copies of the Incident Report will be faxed to committee members for discussion and resolution.

The DCAC tracks the status of each Incident Report using an Incident Follow-up Form (J2). An Incident Report remains 'active' until a final action or resolution has been made, at which time the Incident Report (J1) and the Follow-up Form (J2) are completed and filed. The CTOC and CHIME Engineers assist in evaluating and resolving any Incident Reports which involve technical issues or equipment function.

The Data Safety Monitoring Board is informed of all incidents by Theodore Colton, Sc.D., from the DCAC, either by periodic reports or at yearly meetings.

G. PROCEDURES FOR DOWNLOADING DATA FROM CARTRIDGE TO TEMP DIRECTORY

1. When to download:

Data retrieved from the home should be downloaded to the Base Station and archived for shipment to the DCAC within 24 hours of when it was returned from the field.

2. How to download:

STEP 2 Confirm that the TEMP Directory is empty!

At the Table of Contents, check that the TEMP Directory is empty! If it is, continue with download.

Select T (Data Transfer)

Select D (Download data from cartridge to hard drive). Data from cartridge will be transferred in the hard drive (TEMP directory) of the Computer Base Station.

"New" downloaded data will now appear in the TEMP directory.

STEP 3 Move data in TEMP TO an empty Workstation (W1-W9):

Select T (Data transfer)

Select M (Move) to "Choose Directory to Move From"

Using the Trackball, point to the TEMP directory, click left button once on Trackball.

This will trigger a message: "Choose Directory to Move To". Using the Trackball, point to an empty "workstation" to transfer data.

H. DOWNLOAD REVIEW PROTOCOL

1. Procedures for Downloading and Evaluating Data Quality

STEP #1 Download Data onto Base Station

Once a cartridge has been collected from an infant's home monitor, the data should be downloaded to the Base Station, reviewed and quality evaluated, then archived on DA tape (See Section E. PROCEDURES FOR DOWNLOADING DATA page V-29 for directions) within 48 hours of receipt. A NIMS compliance plot should also be printed out.

STEP 2 Complete STEP # 1 of the H2-DOWNLOAD form

Write in the infant's name, Study ID, the date you are completing the form, your name, the 15 character Event Record Label (ERL) for this download, the date the cartridge was originally **placed in the monitor** for home use and the date it was **removed from the monitor**. Using these two dates, determine the number of days the family had the monitor in the home and write this number down under **Total days monitor available** on **H2-DOWNLOAD**.

For Example: If a cartridge was placed in an infant's monitor on 05/01/94 and removed from the monitor on 05/19/94, the monitor was available for use in the home a total of 17 days. Do not include the days the monitor went into and came out of the home.

STEP 3 Complete STEP # 2 of the H2-DOWNLOAD form

Evaluate the Data Quality for each of the following channels: Abdomen (AB), Chest (RC), ECG, Oximeter (OxiP) and Position (POS). Do this by reviewing at **LEAST 3** wave form files for this download, one from the beginning, one from the middle and one from the end. Document the data quality for each channel as **GOOD, FAIR** or **POOR** on an **H2-DOWNLOAD** Form. If for some reason the cartridge has been damaged and you are unable to download the data, check the category "**Unable to download and evaluate data**".

Definition of **Data Quality** terms:

- Good** = The data is perfect! The channel has interpretable signals for all waveforms reviewed.
Fair = Some waveform files that were reviewed for this channel are uninterpretable.
Poor = All the waveform files reviewed for this channel were uninterpretable.

2. Methods for Evaluating Data for Compliance

STEP 2 Evaluate 8-80 Rule and Complete **STEP #3** of H2-DOWNLOAD

Using the NIMS Compliance Plot, count up the total number of days in which there was at least 8 hours of use. On the **H2-DOWNLOAD** form, under 1) **Number of days with at least 8 hours of use** write in this number. (*NOTE: Each asterisk(*) on the Plot equals 15 minutes of use. Excluding first and last day, eight hours of use is equal to 32 asterisks or more.*) To calculate the **Percent Compliance**, take the **Number of days with at least 8 hours of use**, divide it by the **Total days monitor available** ("A" completed in STEP #1) and multiple by 100.

If compliance is 80% or more, the form is completed and can be sent to the DCAC. If compliance is LESS than 80%, complete 3) **Was compliance already discussed with family in weekly phone contact?** If **NO**, address noncompliance at next weekly phone contact.

STEP 2 8-80 Rule can not be evaluated

If compliance **CAN NOT** be verified because the cartridge can not be downloaded to the base station, on **H2-DOWNLOAD** under Step # 3 **Percent compliance**, check "**can not evaluate**".

3. Compliance Enhancement Protocol

Following each download, study personnel will evaluate compliance as described above. If **8-80 rule** is not met, study personnel will review **H2-WEEKLY** forms to determine if there is noncompliance that has not already been addressed. If noncompliance HAS NOT been addressed (i.e. additional downloads performed), then schedule download in two weeks from last download. At next weekly phone contact, review compliance concerns and provide support/ encouragement, etc. Strategies to enhance compliance include:

- a. Discussing parent concerns.
- b. Review study goals and procedures to improve family's comfort with the study.
- c. Review appropriate family resources; if parent(s)/caregiver(s) are receptive, try to facilitate resource contacts.
- d. If parents are not receptive, or become negative or hostile about expectations, agree with difficulties and attempt to help problem solve. Try to get agreement to continue until next download time.
- e. Re-review situation.
- f. If still non-compliant notify PMD and PI to discuss additional methods to resolve whatever the problem is.

I. Data Archiving and Transfer

1. Data Archiving

Each download of data needs to be backed-up onto **2 DAT Tapes**. One DAT tape will be sent to the DCAC. The other DAT tape will be kept at the local site.

A DAT tape should be sent to the DCAC every week. This DAT tape should contain all of the unscored data downloaded during the past week. Please record the Event Record Labels for each download on the CHIME Event Recording Transmittal Log.

a. Transfer data onto DCAC DAT. The Event Record Label must be retyped for the backup set name on the DAT tape.

(Note: DAT tape must be initialized prior to transfer of first record on DAT.)

b. If a download has no data recorded on it, write the ERL on the CHIME Event Recording Transmittal Log (ERTL) and in comment field write 'No Data Recorded'. You do not need to transfer this data set to DAT tape.

c. Remove DCAC DAT tape from drive and label

d. Verify that DAT is LABELED

- Include Site # and number DATs sequentially

e. Develop "LIBRARY" for local and DCAC DAT Tape Logs

- Use manilla folder to store labeled DAT
Include copy of event logs from DAT in folder
- Label folder with Site#, DAT ID#, and CERTL

f. Repeat procedures **a-e** for local backup DAT tape.

2. Clinical Evaluation of Data

The responsibility of each clinical site is to ensure each infant is provided with appropriate clinical care. Local procedures for clinical review of downloads should be established. Clinical providers should assess the relevance of data on the download.

3. Data Transfer

Mail DATA tapes with the Weekly Packet of data forms and send to **DCAC:**

Rose Dobosz
B.U. School of Public Health
85 E. Newton St., Rm 802
Boston, MA 02118

Phone:(617) 638-5010

APPENDIX V

Cartridge Tracking Form	1
Event Recording Transmittal Log	2
Data Correction Form	3
Equipment Use/Problem Data Flow	4
Monitor Function Test Checklist	5
Equipment Problem Form	6
Example:CHIME Engineers Problem Report	7
Disposable Inventory Form	8
Broken Equipment Transmittal Form	9

CHIME EVENT RECORDING TRANSMITTAL LOG

SITE ID: ____
 SENDER: _____
 DATE SENT: ____/____/____

TRANSMITTAL LOG DATES
 Begin: ____/____/____
 End: ____/____/____

	Event Record Label	Subject Name	# Files	Mb	Initial & Comments
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
16.					
17.					
18.					
19.					
20.					

